

PATENT  
674506-2035.2**REMARKS**

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the remarks herewith.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 96-116 and 125-126 are now pending. Claims 117-124 have been cancelled, and claims 125 and 126 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally and herein presented, are and were in full compliance with the requirements of 35 U.S.C. §112. The new claims, as presented herein, are not added for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, these claims are added for clarification and to round out the scope of protection to which Applicants are entitled.

Support for the amended claims is found in the claims as originally presented and throughout the specification.

**II. THE OBJECTION TO THE SPECIFICATION IS OVERCOME**

The Office Action objects to the specification because claim 9 is allegedly incompletely written. Applicants request that the objection be held in abeyance until such time that the Examiner has had the opportunity to consider the Amendments and remarks herein.

**III. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME**

Claims 96-116 were rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement.

Claims 96-116 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not sufficiently described to enable one of skill in the art to practice the claimed invention.

Claims 96-116 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable one of skill in the art to practice the invention. Applicants respectfully traverse the rejection.

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These rejections all stem from the Office Action's allegation that the specification does not describe the "in vivo" activity of the claimed EPO. Applicants respectfully disagree.

The Examiner's attention is respectfully drawn to Example 9, at page 4, line 29 to page 5, line 11, as introduced in the Amendment filed December 17, 2002, wherein the Example describes the biological activity of EPO, and wherein it is stated that the EPO of the present invention stimulates erythropoiesis and has activity of at least 200,000 U/mg or at least 500,000 U/mg. From the lines mentioned above, it is clear that the activity spoken of in regards to the EPO of the present invention is the biological activity of the EPO, which clearly is "in vivo" activity as it would not be possible to recognize the ability of the EPO of the present invention to stimulate erythropoiesis in any model other than an "in vivo" model.

Accordingly, the "in vivo" activity of the presently claimed EPO is sufficiently described in Example 9, to meet the written description requirement and to provide enablement. Furthermore, the text of Example 9 specifically sets forth references known in the art, such that in combination with the text of Example 9, all of the steps necessary to obtain the EPO of the present invention are provided to enable one of skill in the art to practice the present invention.

Therefore, reconsideration and withdrawal of all of the rejections under 35 U.S.C. §112 is respectfully requested.

#### IV. THE ART REJECTIONS ARE OVERCOME

Claims 96-97 and 99-116 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary and claims 96-116 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively.

Applicants again respectfully assert that Quelle, with or without the evidence provided by Dorland, does not teach or suggest the presently claimed invention; and, Quelle, with or without the evidence provided by Dorland, does not provide any teaching, suggestion, motivation, or incentive to modify the cited document to arrive at the instant invention.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine*

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*Inc. v. Bariant Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). It is also well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, it is respectfully submitted that the instant invention is not anticipated or made obvious by Quelle, *inter alia*, because Quelle does not contain a teaching of all of the elements of the instant claims. And, it is respectfully submitted that the instant invention is not rendered obvious by Quelle, as Quelle does not provide a teaching or suggestion of all of the elements of the instant claims, *inter alia*.

The present invention relates to, *inter alia*, a substantially pure, recombinant glycosylated erythropoietin, produced by a baculovirus expression system in cultured insect cells, wherein said erythropoietin has relative homogeneity or is purified to 95% or greater and said erythropoietin stimulates erythropoiesis and has either an activity *in vivo* of at least 200,000 U/mg or of about 500,000 U/mg, or which has biological activity of at least 200,000 U/mg or of about 500,000 U/mg.

Again, Applicants respectfully assert that the activity described in Example 9 must be "in vivo" activity. Dorland itself may be used to confirm this since it defines erythropoietin as "a glycoprotein hormone secreted chiefly by the kidney in the adult and by the liver in the fetus, which acts on stem cells of the bone marrow to stimulate red blood cell production (erythropoiesis)." Inherent to this definition is that erythropoiesis is an *in vivo* activity and that erythropoietin acts *in vivo* to cause erythropoiesis. Furthermore, as described above, Example 9, at page 4, line 29 to page 5, line 11, as introduced in the Amendment filed December 17, 2002,

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wherein the Example describes the biological activity of EPO, and states that the EPO of the present invention stimulates erythropoiesis and has activity of at least 200,000 U/mg or at least 500,000 U/mg. From this description, it is clear that the activity described in Example 9 regarding the EPO of the present invention is the **biological** activity of the EPO, which clearly is "in vivo" activity as it would not be possible to recognize the ability of the EPO of the present invention to stimulate erythropoiesis in any model other than an **"in vivo"** model.

Furthermore, the Office Action states that the distinctiveness between the presently claimed EPO and that of the prior art is not identified. Again, Applicants disagree. Example 9 specifically states that the glycosylation of EPO is important for its biological activity. Applicants respectfully submit that differences in glycosylation between the presently claimed EPO and that of Quelle account for the differences in biological activity between the two. And, Applicants again point to the previously filed declaration of Dr. Manon Cox that demonstrates the in vivo activity of the presently claimed EPO, which is necessarily different from that which is taught by Quelle.

Therefore, because Quelle does not contain all the elements of the presently claimed invention, and because Quelle does not provide any teaching, suggestion, motivation, or incentive to modify to allow one of skill in the art to arrive at the present invention, it is respectfully requested that the rejections under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

#### **REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner his supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

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**CONCLUSION**

The Amendments and remarks herein place the application in condition for allowance. An early and favorable consideration of the application on the merits, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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